UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,494	10/03/2003	Randall S. Hickle	82021-0044	4564

24633 7590 10/27/2006

HOGAN & HARTSON LLP
IP GROUP, COLUMBIA SQUARE
555 THIRTEENTH STREET, N.W.
WASHINGTON, DC 20004

EXAMINER	
BRANDT, ADAM CURTIS	
ART UNIT	**PAPER NUMBER**
3771	

DATE MAILED: 10/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary	**Application No.** 10/677,494	**Applicant(s)** HICKLE, RANDALL S.	
	Examiner Adam Brandt	**Art Unit** 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☒ Claim(s) ____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date *10/22/2004, 2/25/2004*.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Priority

1. The examiner acknowledges the priority claimed under 35 U.S.C. §119(e) to U.S. Provisional Patent Application No. 60/415,521 filed on 10/3/2002.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 69, 50.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the tongue, as recited in claim 12, depressor must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing

sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hickle (US Pub No.: 2005/0010165 A1) in view of Arndt (US Pub No.: 2001/0015206 A1).

Hickle discloses a sedation and analgesia system comprising:

a patient heath monitor device (12a) adapted so as to be couple to a patient (30) and generate a signal reflecting at least one physiological condition of the patient (55, paragraph 0066);

a drug delivery controller (2a) supplying one or more drugs to the patient;

a user interface (16);

an electronic controller (14) interconnected with the patient health monitor, the user interface and the drug deliver controller, wherein said electronic controller receives said signal and in response to said signal manages the application of the drugs (paragraph 0073).

While Hickle discloses a facemask (30) that couples to the patient, Hickle fails to disclose a bite block. Arndt discloses a bite block (10) comprising a bite portion (20) and an opening to access the patient's mouth (Area near 14). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the bite block of Arndt with the system of Hickle so that mouth region can be accessed if needed.

Additionally, it is well known in the art to use a bite block and a facemask in combination (Arndt, paragraph 0033).

9. Claims 1, 2, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickle in view of Weaver (5,413,095).

Hickle discloses a sedation and analgesia system comprising:

a patient heath monitor device (12a) adapted so as to be couple to a patient (30) and generate a signal reflecting at least one physiological condition of the patient (55, paragraph 0066);

a drug delivery controller (2a) supplying one or more drugs to the patient;

a user interface (16);

an electronic controller (14) interconnected with the patient health monitor, the user interface and the drug delivery controller, wherein said electronic controller receives said signal and in response to said signal manages the application of the drugs (paragraph 0073).

While Hickle discloses a facemask (30) that couples to the patient, Hickle fails to disclose a bite block. Weaver discloses a bite block (10) comprising a bite portion (12) and an opening to access the patient's mouth (14). Weaver further discloses channels (20) that a pair of nasal cannulae can be used to directed gas from a source through the channels to the mouth in order to receive a sedative. It would be reasonable to one of ordinary skill in the art to use the channels via nasal cannula as a viable alternative to a facemask for passing gas to a patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the bite block of Arndt with the system of Hickle so that mouth region can be accessed if needed during surgical procedures.

In regard to claim 2: Weaver discloses a bite block that comprises at least one channel (20) extending through said bite portion.

In regard to claim 13: Hickle discloses a sedation and analgesia system, comprising:

a patient heath monitor device (12a) adapted so as to be couple to a patient (30) and generate a signal reflecting at least one physiological condition of the patient (55, paragraph 0066);

a drug delivery controller (2a) supplying one or more drugs to the patient;

a user interface (16);

a gas monitoring and delivery system (2) supplying one or more types of gas to the patient (paragraph 0081);

an electronic controller (14) interconnected with the patient health monitor(12a), the user interface(16), gas monitoring and delivery system (2), and drug delivery controller (2a), wherein said electronic controller receives said signal and in response to said signal manages the application of the drugs (paragraph 0073).

While Hickle discloses a facemask (30) that couples to the patient, Hickle fails to disclose a bite block. Weaver discloses a bite block (10) comprising a bite portion (12) and an opening to access the patient's mouth (14). Weaver further discloses channels (20) that a pair of nasal cannulae can be used to directed gas from a source through the channels to the mouth in order to receive a sedative. It would be reasonable to one of ordinary skill in the art to use the channels via nasal cannula as a viable alternative to a facemask for passing gas to a patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the bite block of Arndt with the system of Hickle so that mouth region can be accessed if needed during surgical procedures.

10. Claims 3-8, 10-12, 14-17, 19, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickle in view of Weaver as applied in claims 2 and 13 above and further in view of Shepherd (US Pub. No.: 2002/0028990).

Hickle and Weaver disclose the system of claim 2. Weaver discloses a channel (20), but fails to mention that a sensor is located in the channel. Shepherd teaches that a sensor (20, 22) located can be located in a channel(240) and have at least one of a sensor (20, 22) and a sampling port (openings through which oximeter diodes 20 and 22 emit) connected to a sensor for monitoring gases passing through said at least one channel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Shepard by placing a sensor in the channel of a bite block as disclosed by Hickle and Weaver for the purpose of monitoring the condition of the patient with out the need for any auxiliary sensors.

In regard to claim 4: Shepherd further discloses the system wherein said at least one channel is used for at least one or respiratory rate monitoring, oxygen concentration monitoring (oximeter 20, 22), positive and negative respiratory pressure monitoring, temperature monitoring, humidity monitoring, and respiratory flow monitoring..

In regard to claim 5: Hickle discloses the system wherein said electronic controller alters said drug delivery based on said patient's conditions as monitored by said sensors (paragraph 0032).

In regard to claim 6: Weaver discloses the system wherein said at least one channel of said bite block provides an inlet for gas delivery (col. 3, ln. 67-64).

In regard to claim 7: Hickle further comprising a gas source (paragraph 0078) and a gas monitoring and delivery system (2).

In regard to claim 8: Weaver discloses the system wherein said nasal cannula (26) such that gas from said nasal cannula passes through said channel into said patient's mouth (col. 3, ln. 53-64).

In regard to claim 10: Hickle and Weaver combine to disclose (as presented in claim 3) said at least one channel comprises at least one of a sensor of a sensor and sampling port connected to a sensor for monitoring gas output from said gas supply through said at least one channel. Hickle presents in paragraph 0012, the system monitors inhaled gases which is from said gas supply.

In regard to claim 11: Hickle discloses (paragraph 0032) said electronic controller alters delivery of gas from said supply based on said patient's conditions as monitored by said sensors.

In regard to claim 12: Weaver discloses in figure 3 said bite block that comprises a tongue depressor (exterior tube of 240 in the are of the tongue) extending into the patients mouth, wherein the tongue depressor holds down the patient's tongue and prevents the patient from using their tongue to push out the bit block. It is obvious from the figure that the bite block's overlays the tongue and that the bite block would securely restrain the tongue when the patient is placing force on the bite block with their teeth.

In regard to claim 14: Hickle and Weaver disclose the system of claim 13. Weaver discloses a channel (20), but fails to mention that a sensor is located in the channel. Shepherd teaches that a sensor (20, 22) located can be located in a channel(240) and have at least one of a sensor (20, 22) and a sampling port (openings through which oximeter diodes 20 and 22 emit) connected to a sensor for monitoring gases passing through said at least one channel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Shepard by placing a sensor in the channel of a bite block as disclosed by Hickle and Weaver for the purpose of monitoring the condition of the patient with out the need for any auxiliary sensors.

In regard to claim 15: Shepherd discloses in paragraph 0106 said sensors are wirelessly integrated with said electronic controller.

In regard to claim 16: Hickle discloses (paragraph 0032) said electronic controller alters delivery of gas from said supply based on said patient's conditions as monitored by said sensors.

In regard to claim 17: Weaver discloses in figure 3 said bite block that comprises a tongue depressor (exterior tube of 240 in the are of the tongue) extending into the patients mouth, wherein the tongue depressor holds down the patient's tongue and prevents the patient from using their tongue to push out the bit block. It is obvious from the figure that the bite block's overlays the tongue and that the bite block would securely restrain the tongue when the patient is placing force on the bite block with their teeth.

In regard to claim 19: Hickle discloses a sedation and analgesia system (2). The bite block of Weaver modified by the teachings of Shepherd yield a bite block with functionalities that can be integrated with said sedation and analgesia system; Hickle's system provides computer programming capable of comparing patient data and a controller that adjusts the gas delivered to a patient (Hickle paragraph 0029). The method steps would have been obvious because they would have resulted from the use of he device of Hickle/Weaver/Shepherd.

In regard to claim 20: Hickle discloses electrical leads (figure 3a, power cord), gas delivery tubes (figure 1, tubes entering facemask), fluid delivery tubes (figure 1, tubes entering face mask). The method steps would have been obvious because they would have resulted from the use of the device of Hickle.

11. Claims 9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickle in view of Weaver as in view of Shepherd as applied to claims 3-8, 10-12, 14-17, 19, 20 above, further in view of Jackson (5,513,634).

Hickle, Weaver, and Shepherd fail to disclose nasal cannula comprising both oral delivery chambers to connect to said bite block and nasal delivery chambers. Jackson discloses a bite block with nasal cannula delivery chambers (50;51) connected to the bite block (see figure 2) with an opening centrally located in the bite block that operates as an oral delivery chamber. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the modified sedation and analgesia system of Hickle with nasal connector and oral delivery as taught by Jackson so that both a feeding tube could be inserted and nasal cannula could be used simultaneously.

In regard to claim 18: Hickle, Weaver, and Shepherd fail to disclose a bite block integrated with a nasal cannula such that at least one of gases, fluids, and drugs can be delivered to the patient both nasally and orally. Jackson discloses a bite block with nasal cannula delivery chambers (50;51) connected to the bite block (see figure 2) with an opening centrally located in the bite block that operates as an oral delivery chamber that could administer drugs, fluids, or gasses. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the modified sedation and analgesia system of Hickle with nasal connector and oral delivery as taught by Jackson so that both a oral medication could be administered as well as a nasal gasses simultaneously.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Solesbee et al. (5,485,837); Reif (5,479,921); James (5,558,090); Weil et al. (6,071,237); Schmidt et al. (US 2003/0145852); Wilkie et al. (US 2003/0172936); Antenbring et al. (6,655,384); McDonald (6,837,238); Hickle (6,938,619); Christopher (7,063,088); Wright (US 2006/0207597); Fisher (4,895,143); Borody (5,273,032); Press (5,375,593); Thornton (5,983,892); Scarberry et al. (US 2001/0015206); Lim (US 2005/0239017); McCormick et al. (US 2005/0247316); Orr (US 2005/0247316); Cannon (7,021,312); Bruggeman et al.(US 2006/0081259); Glazer (7,090,395); Goldstein (5,752,510); Thornton (6,405,729).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Brandt whose telephone number is 571-272-7199. The examiner can normally be reached on 8:30 AM to 4:30 PM; Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Adam Brandt

Adam Brandt
Examiner
Art Unit 3771

ACB

JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

10/25/06